

I. LISTING OF THE CLAIMS

1. (PREVIOUSLY PRESENTED) An apparatus for lancing the skin of a test subject, collecting a body fluid sample from the lanced site on the skin of the test subject, the apparatus comprising:

a body having an open end;

a hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel for moving a fluid sample from the tip to a reaction area;

a lancing mechanism disposed within the body, the lancing mechanism coupled to the lancet at an end of the lancet opposite the tip, the lancing mechanism being adapted to move the lancet between a retracted position, a lancing position for puncturing the skin of a test subject, and a collection position for collecting the body fluid sample;

an outer end cap having a first end coupled to the open end of the body and a second end for contacting the skin of the test subject, the outer end cap forming a first aperture therein that the tip of the lancet enters when in the lancing position, the outer end cap having a wall extending to the second end thereof; and

an inner end cap disposed within the outer end cap, the inner end cap having a first end coupled to the open end of the body and a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof, the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap,

wherein the second end of the outer end cap and the second end of the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.

2. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet comprises fused silica.

3. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet has a polygonal cross-section.

4. (ORIGINAL) The apparatus of claim 1 further comprising a vacuum member for evacuating air from the inner and outer end caps, the vacuum member being adapted to position the skin of the test subject against the second end of the inner end cap.

5. (ORIGINAL) The apparatus of claim 4 wherein the vacuum member comprises a diaphragm.

6. (ORIGINAL) The apparatus of claim 4 wherein the vacuum member comprises bellows.

7. (PREVIOUSLY PRESENTED) The apparatus of claim 1 further comprising:
a light source for illuminating the reaction of the reagent and the analyte in the body fluid sample; and
a light detector for detecting light transmitted through the reaction.

8. (CANCELLED)

9. (CANCELLED)

10. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet has a square or rectangular cross-section.

11. (ORIGINAL) The apparatus of claim 1 wherein the retracted position and the collection position are substantially the same.

12. (PREVIOUSLY PRESENTED) A method for lancing the skin of a test subject and collecting a body fluid sample from the lanced site on the skin of the test subject for determining the concentration of an analyte in the body fluid sample with a lancing and collection device, the lancing and collection device including a hollow lancet having a tip for puncturing skin, the method comprising the acts of:

placing an outer end cap of the device against the skin of a test subject;
puncturing the skin with the lancet in a lancing position;

positioning the punctured skin against an edge of an inner end cap of the device, the inner end cap being disposed within the outer end cap;

disposing the tip of the lancet a predetermined distance from the skin pulled against the edge of the inner end cap; and

collecting the body fluid sample from the puncture skin with the tip of the lancet in a collection position,

wherein the outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.

13. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the hollow lancet includes a reaction area with a reagent adapted to produce a colorimetric reaction indicative of the analyte concentration in the sample, the method further comprising the acts of moving the collected body fluid sample from the tip of the lancet to the reaction area via capillary action.

14. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the analyte is glucose.

15. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the body fluid sample is blood.

16. (PREVIOUSLY PRESENTED) The method of claim 13 further comprising the act of measuring a colorimetric reaction.

17. (PREVIOUSLY PRESENTED) The method of claim 16 wherein the act of measuring further comprises the acts of:

illuminating the colorimetric reaction within a hollow, substantially clear lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

18. (PREVIOUSLY PRESENTED) The method of claim 17 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

19. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the act of positioning further comprising the act of evacuating the air from the inner end cap with a vacuum member of the device.

20. (PREVIOUSLY PRESENTED) The method of claim 12 further including analyzing the body fluid sample for determining the analyte concentration in the body fluid sample while the collected body fluid sample remains in the lancet.

21. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the capillary channel of the hollow lancet has an inlet, and the act of collecting further comprises positioning the inlet of the capillary channel adjacent the lanced skin.

22. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the lancing device includes an end cap, the method further comprising the act of positioning the skin against the end cap for maintaining the skin in a fixed position.

23. (PREVIOUSLY PRESENTED) The method of claim 22 wherein the act of positioning further comprises the act of activating a vacuum member.

24. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the method further comprises the act of maintaining the skin in a fixed position while collecting the body fluid sample.

25. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the capillary channel contains a reagent for reacting with the analyte in the body fluid sample and producing a colorimetric reaction indicative of the concentration of the analyte in the body fluid sample.

26. (PREVIOUSLY PRESENTED) The method of claim 25 wherein the act of analyzing further comprises the act of optically analyzing the body fluid sample.

27. (PREVIOUSLY PRESENTED) The method of claim 26 wherein the act of optically analyzing comprises the acts of:

illuminating the colorimetric reaction within the hollow lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

28. (PREVIOUSLY PRESENTED) The method of claim 27 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

29. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the hollow lancet is substantially optically clear.

30. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a polygonal cross section.

31. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a rectangular cross section.

32. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a square section cross section.

33. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the analyte is glucose.

34. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the body fluid sample is blood.

35. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the inner end cap remains entirely disposed within the outer end cap during the retracted position, the lancing position and the collection position.